

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler

This relates to: All Actions

PLAINTIFFS' REPLY IN SUPPORT OF
PLAINTIFFS' MOTION TO EXCLUDE OPINIONS OF
JOHN FLACK, M.D., M.P.H.

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INTRODUCTION

The absence of evidence is *not* evidence—despite Defendants’ attempts to make it so. John Flack, M.D., M.P.H., proposes to offer testimony that he cannot support with scientific studies, a review of patient datasets, or personal experience. The absence of this evidence and experience is not in dispute.

did not review any [REDACTED] (if any) took nitrosamine-containing VCDs,² and had no experience with the inner-workings of third-party payors (TPPs).³ Defendants merely dispute that an expert needs such evidence or experience to support their conclusions. Rule 702 says otherwise.

First, Defendants assert that Dr. Flack’s failure to identify even one study comparing the efficacy of nitrosamine-containing VCDs to non-nitrosamine-containing VCDs somehow constitutes evidence that they are equally efficacious.⁴ Defendants likewise claim that Dr. Flack has personal knowledge that both drugs were equally efficacious based on his clinical observations⁵ [REDACTED]

[REDACTED] Rule 702 is clear, however, that in the absence of scientific studies, other reliable methodology must be [REDACTED]

[REDACTED]

¹ Ex. 1, Flack Tr. (Feb. 1, 2023), 26:16–20, 52:18–24, 53:08–54:02, 63:20–21.

² Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–11, 44:17–24.

³ Ex. 1, Flack Tr. (Feb. 1, 2023), 55:13–56:17.

⁴ Def.’s Mem., at 2.

⁵ Def.’s Mem., at 12.

⁶ Ex. 1, Flack Tr. (Feb. 1, 2023), 39:02–08, 44:02–05.

⁷ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–11, 44:17–24.

⁸ *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp.3d 262, 273 (E.D. Pa. 2021).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Flack's arbitrary decision to ignore important facts renders his opinion that the recall did not negatively affect patients unreliable.¹²

Finally, Dr. Flack's opinion as to what TPPs would have done in a hypothetical scenario if valsartan was otherwise unavailable must be excluded as pure speculation by an individual who has no relevant experience with TPPs and is therefore unqualified to opine as to how they would act in any scenario, let alone a fictional one. This opinion is, moreover, irrelevant to any claim or defense in this action.

Accordingly, Dr. Flack's opinions should be excluded in their entirety.

LEGAL STANDARD

"Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). The proponent of expert testimony bears the burden of establishing that the testimony meets this standard "by a preponderance of proof." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 593 n.10 (1993)). With respect to the reliability

⁹ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:02–24, 45:02–16, 53:98–24.

¹⁰ Ex. 1, Flack Tr. (Feb. 1, 2023), 13:08–15, 20:18–21:07, 24:13–17, 26:02–20, 26:21–29:03.

¹¹ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–11, 44:17–24.

¹² *In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 796 (3d Cir. 2017) ("[T]he assessment or weighing of that evidence must not be arbitrary but must itself be based on methods of science."); *Player v. Motiva Enter. LLC*, No. Civ. 02–3216(RBK), 2006 WL 166452, at *6–7 (D.N.J. Jan. 20, 2006).

requirement, “the expert’s opinion must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’” that is, their opinion must be supported by “good grounds.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert*, 509 U.S. at 580)). For this reason, the Third Circuit explained, “inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity.” *Id.*

ARGUMENT

I. Dr. Flack’s Opinion that Nitrosamine-Containing VCDs Are Equally Effective as Non-Nitrosamine-Containing VCDs Lacks a Reliable Methodology

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Defendants argue that this complete lack of evidence is not fatal to his opinions but is, curiously,

¹³ Ex. 1, Flack Tr. (Feb. 1, 2023), 52:18–53:7, 60:21–61:5 and 63:22–64:5; Ex. 2, Flack Rep. (Dec. 19, 2022), at 10–11, 16.

¹⁴ *Id.*

¹⁵ Ex. 1, Flack Tr. (Feb. 1, 2023), 26:16–20, 52:18–24, 53:08–54:02, 63:20–21.

¹⁶ Ex. 1, Flack Tr. (Feb. 1, 2023), 26:16–20, 52:18–24, 53:08–54:02, 63:20–21.

¹⁷ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–11, 44:17–24.

a positive.¹⁸ However, their interpretation is inconsistent with the *Daubert* standard.

1. Dr. Flack's Determination that the Absence of Evidence Somehow *Is* Evidence is Not Methodologically Sound

Defendants assert, “as Dr. Flack explained, the lack of studies showing that the presence of trace nitrosamines impacted the efficacy of VCDs *is evidence* that it did not.”¹⁹ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Further, in making the assertion that there was “no” evidence of a difference between nitrosamine-containing and non-nitrosamine-containing VCDs, Dr. Flack failed to ever consider the actual studies conducted by the Defendants. For example, Aurobindo,²¹ Teva,²² and Princeton²³ concluded that their VCDs were “not bioequivalent” for valsartan. Far from being methodologically sound, this practice is both speculative and fallacious. With such studies not having been conducted, Dr. Flack cannot say with any reasonable basis what they would conclude. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (“subjective belief or unsupported speculation” is unreliable) (quotation omitted). Moreover, the proposition that something is true merely because

¹⁸ Def.’s Mem., at 9–10.

¹⁹ Def.’s Mem., at 6.

²⁰ Ex. 1, Flack Tr. (Feb. 1, 2023), 26:16–20, 52:18–24, 53:08–54:02, 63:20–21.

²¹ Aurobindo’s internal study concluded that, “Valsartan 320 mg Tablets (Test) of Aurobindo Pharma Ltd., India is ***not-bioequivalent*** to Diovan 320 mg tablets”. (Ex. 3, emphasis added).

²² Teva came to the same conclusion about their VCDs at issue, “results for the Valsartan and [Redacted] 160 mg and 25 mg fasted study. Unfortunately, the results indicate we are ***not bioequivalent*** for valsartan.” (Ex. 4, emphasis added)

²³ Princeton Pharmaceutical came to the same conclusion about their VCDs at issue, “Valsartan 320 mg tablets, Manufactured by Huahai Pharmaceutical Co., Ltd., Zhejiang, China is ***not bioequivalent*** to Reference formulation i.e., Diovan® (Valsartan Tablets 320 mg), Distributed by Novartis Pharmaceutical Corp., East Hanover, Nj 07936 in normal, healthy, adult, human subjects under fasting condition.” (Ex. 5, emphasis added).

it cannot be disproven is a logical fallacy. Like Dr. Flack, Defendants have not—and cannot—identify any authority to support their argument. Defendants failed to identify a single court in which the *absence* of evidence was allowed to stand as affirmative evidence in support of a proposition. To the contrary, the cases cited by Defendants show that where experts lack scientific literature to back up their claims, courts required other reliable evidence—but the “absence” of evidence has never been enough.

First, Defendants cite *In re Asbestos* for the proposition that “epidemiology studies are not *per se* required and may not be needed *if* an expert offers a reliable . . . opinion through the use of some other valid scientific methodology.” *In re Asbestos Prods. Liability Litig. (No. VI)*, 714 F.Supp.2d 535, 544 (E.D. Pa. 2010).²⁴ Defendants miss the point of that decision. Whereas the expert in *In re Asbestos* relied on other scientific data that *affirmatively* supported their conclusions, including case reports, animal studies, and migration studies, *id.* at 543, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Second, Defendants’

reliance on *State Farm Fire & Cas. Co. v. Hartman Contrs.*, 2017 WL 2180292, (E.D. Pa. May 18, 2017), is misplaced. While the court in that case rejected the argument that an expert lacked evidentiary support, the facts were completely distinguishable from the present case. [REDACTED]

[REDACTED]

²⁴ Def.’s Mem., at 12.

²⁵ Ex. 1, Flack Tr. (Feb. 1, 2023), 26:16–20, 52:18–24, 53:08–24, 60:21–62:05, 63:18–21.

²⁶ Ex. 1, Flack Tr. (Feb. 1, 2023), 53:08–24.

[REDACTED],²⁷ the opinions in *State Farm* were based on an in-person investigation of a physical premises. *Id.* at *7. Finally, Defendants ignore the holding in *Hoefling v. U.S. Smokeless Tobacco Co., LLC.*, 576 F. Supp.3d 262, 273 (E.D. Pa. 2021). The court in *Hoefling* held that an expert’s opinion was unreliable because it lacked support from epidemiological data. 576 F. Supp.3d 262, 273 (E.D. Pa. 2021). The court emphasized that, in the absence of such data, there must be “other factors that demonstrate the reliability of an expert’s methodology,” but—just as in Dr. Flack’s opinions—such evidence was absent. *Id.* at 274 (quotations omitted).

Contrary to Defendants’ assertions, it has never been the rule in this Circuit that an expert may proffer their opinions without any evidence whatsoever. Rather, where there are no published studies, an expert’s opinions must be based on other “scientifically methods.” *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d. Cir. 1999). When an expert has no studies to support their proposition *and* does not have any other scientifically valid methodology to support their conclusions, their “opinion does not rise above subjective belief or unsupported speculation.” *Meyers v. Gwin Dredging & Dock, Inc.*, 2005 WL 8175914, at *3 (D.N.J. Dec. 20, 2005).

His bare assertions that the absence of evidence is enough—without any other reliable evidence to support his claims—render his opinions unreliable.

2. Dr. Flack's Observations are Not a Reliable Basis for a Comparison Between Nitrosamine-Containing and Non-Nitrosamine-Containing VCDs Where Dr. Flack has "No Way of Knowing" Which VCDs his Patients Consumed

²⁷ Ex. 1, Flack Tr. (Feb. 1, 2023), 26:16–20, 52:18–24, 53:08–24, 60:21–62:05, 63:18–21.

²⁸ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:02–24, 45:02–16, 53:98–24.

Defendants’ attempts to portray Dr. Flack as offering opinions based on “personal knowledge”²⁹ collapse in the face of Dr. Flack’s unequivocal testimony [REDACTED]

[REDACTED]

Though no such statement appears in the record,³¹ Defendants now claim that Dr. Flack’s clinical observations about the efficacy of nitrosamine-containing VCDs as compared to non-nitrosamine-containing VCDs, were regarding “the clinical effectiveness of the VCDs in his patients *across the board* during the relevant period.”³² [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁹ Def.’s Mem., at 15–16.

³⁰ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:17–24; *see also* Flack Tr., 39:02–08, 44:06–11.

³¹ *See, e.g.*, Ex. 2, Flack Rep. (Dec. 19, 2022); Flack Tr. (Feb. 1, 2023).

³² Def.’s Mem., at 2 (emphasis original).

³³ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–11, 44:17–24.

³⁴ Ex. 1, Flack Tr. (Feb. 1, 2023), 29:23–30:10, 50:11–51:19; Ex. 2, Flack Rep (Dec. 19, 2022), at 8–9.

³⁵ Ex. 1, Flack Tr. (Feb. 1, 2023), 33L22–34:20.

³⁶ Ex. 1, Flack Tr. (Feb. 1, 2023), 39:02–08, 44:02–05.

³⁷ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–11, 44:17–24.

Other than a vague reference to his personal experience,³⁹ Dr. Flack did not identify *any* data or method by which he was able to make this determination. But that is not enough under *Daubert. Freedom Mortgage Corp. v. LoanCare, LLC*, 2023 WL 2570201, at *10 (D.N.J. Mar. 20, 2023) (holding that where an expert cannot point to reliable data, their “intended testimony is too speculative to survive scrutiny.”).

Even the authorities Defendants themselves rely on emphasize that “personal experience” or “personal knowledge” are issues of qualification but do not serve as adequate substitutes for a reliable methodology where an expert is providing a *scientific* opinion. Analyzing an expert’s qualifications, rather than their methodology or the bases for their opinion, the court in *O’Bryant v. Johnson & Johnson*, 2022 WL 7670296, *6 (D.N.J. Oct. 13, 2022), stated that an expert “need not be precisely informed about all details,” and accordingly allowed an expert who was “not retained to discuss the intricacies of prolapse surgery” but rather who was qualified in the areas of chronic pain to offer opinions as to the causation of the plaintiff’s surgical pain. The *O’Bryant* court did not, as Defendants would suggest, permit an expert to rely on qualification *alone* to render opinions about the effect of a treatment on patients that expert had never observed and could never observe.⁴⁰

³⁸ Ex. 1, Flack Tr. (Feb. 1, 2023), 6:23–64:05

³⁹ Ex. 2, Flack Rep (Dec. 19, 2022), at 11.

⁴⁰ Defendants’ citation to *Stokes v. Janosko*, 2018 WL 3361456, *3 (W.D. Pa. July 10, 2018) is taken entirely out of context. While Defendants cite *Stokes* for the proposition that experts may rely on personal experience, the court in fact held “where an expert is proffered to testify regarding *non-scientific* matters, the relevant reliability concerns will focus upon personal knowledge and experience of the witness and the methodology used will be applying that experience to the facts of the case.” *Id.* (emphasis added). Dr. Flack was not performing a technical investigation, but rather providing a “clinical” opinion and his general references to personal experience are insufficient under *Daubert*.

[REDACTED]¹ [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

II. Dr. Flack's Opinions that Patients Taking VCDs Were Not Affected by the Recall Disregarded Important Facts Without Explanation

In rendering the opinion that patients taking VCDs were not affected by the recall, Dr. Flack impermissibly disregarded numerous facts critical to understanding the recall's impacts on patients without explanation. *Player v. Motiva Enterprises LLC*, 2006 WL 166452, at *6–7 (D.N.J. Jan. 20, 2006). [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁴¹ Ex. 1, Flack Tr. (Feb. 1, 2023), 44:06–15, 47:14–48:07, 54:03–11.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Ex. 1, Flack Tr. (Feb. 1, 2023), 13:21, 51:20–52:14.

⁴⁵ Ex. 1, Flack Tr. (Feb. 1, 2023), 13:08–15, 20:18–21:07, 24:13–17, 26:02–20, 26:21–29:03.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The failure to consider important facts without explanation is grounds to exclude an expert's testimony as unreliable. *Player*, 2006 WL 166452, at *7. Defendants argue that *Player* is inapposite because the opinions of the expert in that case ran afoul of *Daubert* for multiple reasons including, like Dr. Flack's opinions, because they were untestable and arbitrary,⁴⁷ but this does not mean that experts are free to simply *ignore* relevant facts in rendering their opinions. *See In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F.Supp. 449, 461–62 (E.D. Pa. 2014) (“cherry picking is always a concern.”). For example, in *Zolofit*, the court emphasized that an expert's conclusions “drawn from trends she observed in a self-selected subset of studies, not the totality” of evidence available “further underscore[d] her problematic methodology.” *Id.* Here, too,

[REDACTED]

[REDACTED]

[REDACTED] is not a reliable methodology and this opinion must be excluded.

III. Dr. Flack's TPP Opinions are Not a Fit for this Litigation and are Beyond the

⁴⁶ Ex. 1, Flack Tr. (Feb. 1, 2023), 30:15–31:02.

⁴⁷ *See supra* section I.

⁴⁸ Ex. 1, Flack Tr. (Feb. 1, 2023), 13:08–15, 20:18–21:07, 24:13–17, 26:02–20, 26:21–29:03.

Scope of his Expertise

Though Defendants assert Dr. Flack “appl[ied] his experience to the facts of the case,”⁴⁹ by his own admission, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] He nonetheless, concluded that if the VCDs were otherwise unavailable during the 2012–2018 period, “TPPs would have paid for . . . alternative medications” prescribed by healthcare practitioners.”⁵³ As an initial matter, this opinion is irrelevant to any claim or defense in this litigation, and therefore, should be excluded pursuant to Rule 702, because there is no “fit” between the opinion and “particular disputed factual issues in the case.” *In re Paoli R.R. Yard PCB Litig.*, 3 F.3d 717, 743 (3d Cir. 1994) (quotations omitted). Moreover, Dr. Flack is unqualified to testify as to the inner workings of TPPs, including the medications that they pay for and the decisions they make regarding payment. However, Dr. Flack’s TPP opinion goes even further than testimony as to what TPPs do or have done (which is outside his scope) and stretches into pure speculation about what TPPs would have done in a hypothetical scenario that never occurred. This opinion should be excluded for the additional reason that it is based on “subjective belief or unsupported speculation.” *Paoli*, 35 F.3d at 742 (quoting *Daubert* 509 U.S. 579, 580 (1993)).

⁴⁹ Def.’s Mem., at 21 (quoting 2018 WL 3361456, *3 (W.D. Pa. July 10, 2018))

⁵⁰ Ex. 1, Flack Tr. (Feb. 1, 2023), 55:10–12.

⁵¹ Ex. 1, Flack Tr. (Feb. 1, 2023), 56:21–57:02.

⁵² Ex. 1, Flack Tr. (Feb. 1, 2023), 55:13–56:17.

⁵³ Ex. 2, Flack Rep. (Dec. 19, 2022), at 17.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the opinions of John Flack, M.D., M.P.H. be excluded in their entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 24, 2023, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

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